Paper 8

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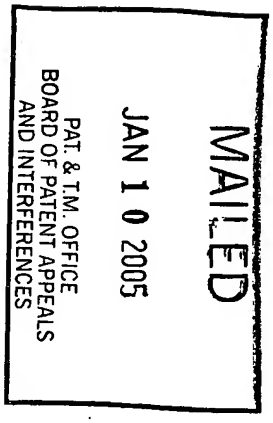
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES



HANS **PETERSEN**
and
MICHAEL HAROLD ROCK
(Application 09/794,755)

Junior Party,

v.

TETSUYA **IKEMOTO**, WEI-GUO GAO,
and
MASAMI IGI
(Application 10/086,076)

Senior Party

Patent Interference 105,075

Before McKELVEY, Senior Administrative Patent Judge, SCHAFER, and MOORE, Administrative Patent Judges.

MOORE, Administrative Patent Judge.

DECISION ON PRELIMINARY MOTIONS - Bd. R. 125(a)

A. Background

This interference is before us for decision on the preliminary motions of the parties. This decision addresses the following two preliminary motions, which are dispositive of this interference.

(I) Ikemoto Preliminary Motion 2 (Paper 50) seeks judgment pursuant to 37 CFR §1.633(g) [now 37 CFR §41.121(a)(2)] that Petersen is not entitled to benefit of the filing date of Danish Patent Application PA 2000 00296, filed February 24, 2000, for count 1 and Petersen claims 6 and 7 of 09/794,755.

(II) Ikemoto Preliminary Motion 3 (Paper 51) seeks judgment pursuant to 37 CFR §1.633(a) [now 37 CFR §41.121(a)(1)(iii)] that Claims 6 and 7 of Petersen 09/794,755 are unpatentable under 35 U.S.C. §102 as anticipated.

We **DENY** Ikemoto's Preliminary Motion 2

We **GRANT** Ikemoto's Preliminary Motion 3.

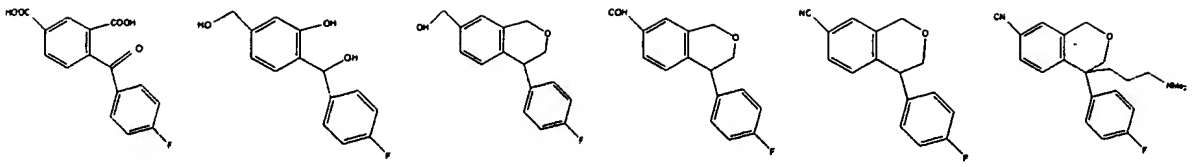
B. Findings of Fact

1. This interference was declared November 7, 2003 (Paper 1, page 1).

2. Junior Party Petersen is involved by virtue of its application 09/794,755 (see Paper 1, page 3).

3. Senior Party Ikemoto is involved by virtue of its application 10/086,076 (see Paper 1, page 4).

4. The interference involves a process for the preparation of citalopram involving the following compounds and steps. For sake of consistency, the compounds and steps to form the compounds shall be referenced herein as follows. Compound 6 is citalopram.



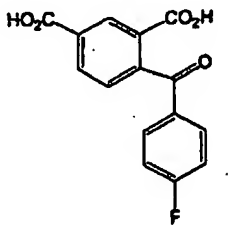
Compound 1 Compound 2 Compound 3 Compound 4 Compound 5 Compound 6

reducing (step 1) cyclizing (step 2) oxidizing (step3) converting(step 4) alkylating (step 5).

5. Count 1 of this interference reads as follows:

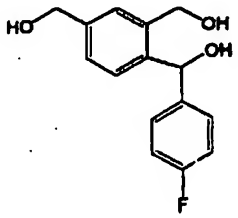
A method for the preparation of [Compound 6], comprising the steps of:

a) reducing [Compound 1]



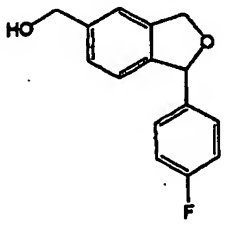
(1)

to form [Compound 2]



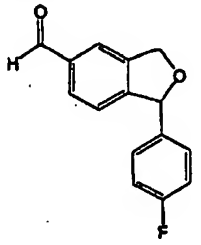
(2)

b) cyclizing or ring closing [Compound 2] to form [Compound 3]



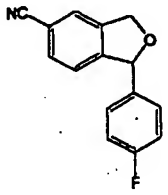
(3)

c) oxidizing [Compound 3] to form [Compound 4]



(4)

d) converting [Compound 4] to [Compound 5]



(5)

and

e) (1) alkylating [Compound 5] to form [Compound 6] as an acid or base addition salt thereof, or

e) (2) alkylating [Compound 5] to form [Compound 6]; and isolating [Compound 6] in the form of the base or an acid addition salt thereof. (Paper 1, pages 5-6).

6. Ikemoto Patent 6,433,196 was filed September 5, 2000 and issued August 13, 2002. (Paper 51, fact 3; admitted at paper 60, page 3, lines 6-8).

7. Ikemoto '196 discloses a reaction involving the compounds outlined in fact 4.

8. Ikemoto '196, column 9, lines 8-20, describes a reduction step of Compound 1 which results in Compound 2.

9. Ikemoto '196, column 11, line 57 – column 12, line 12, describes that the Compound 3 can be oxidized to Compound 4 with high yield.

10. Ikemoto '196, column 13, lines 57-column 14, line 30, describes that Compound 4 may be converted by oximation and dehydration to Compound 5.

11. Ikemoto column 14, lines 47 et seq., describes the alkylation of Compound 5 to form Compound 6 - citalopram.

12. Petersen Danish Patent Application 2000-00296 (Exhibits 2008 and 1003) describes the 5 step process for going from compound 1 to compound 5 is disclosed as another "advantageous method" at page 7, lines 20-40.

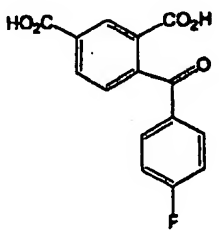
13. Petersen Danish Patent Application 2000-00296 describes the conversion of 5-cyano-1-(4-fluorophenyl)-1,3-dihydrobenzofuran [Compound 5] by alkylation followed by conversion of the alkyl group to a dimethylaminopropyl group to citalopram [Compound 6] at page 2, line 10 – page 3, line 4.

14. One of ordinary skill in the art as of February 24, 2000 would have been either (I) a person with at least a bachelor's degree in chemistry with specialty in organic synthesis; and 1-2 years of experience in organic synthesis if not that specialty (Exhibit 2011, paragraph 4) or (II) a person with a BS degree in chemistry (Exhibit 1019, paragraph 3). This person would have knowledge of organic synthesis, including reactions and mechanisms.

15. The art is not completely predictable, in that unexpected results are still obtained. (Exhibit 2008, page 2, lines 1-3).

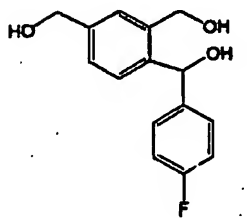
16. Petersen claim 6 reads as follows:

6. A method for preparing citalopram, comprising the steps of reducing [Compound 1]



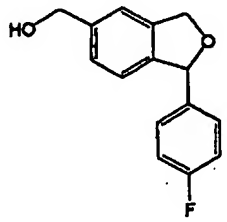
[(1)]

to form [Compound 2]



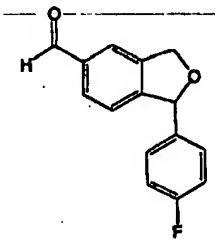
[(2)]

subjecting [Compound 2] to ring closure to form [Compound 3]



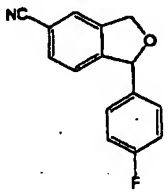
[(3)]

oxidizing [Compound 3] to form [Compound 4]



[(4)]

converting [Compound 4] to [Compound 5]



[(5)]

alkylating [Compound 5] to form [Compound 6]; and

isolating [Compound 6] in the form of a base or an acid addition salt thereof.

17. Petersen Claim 7 reads as follows:

7. The method of claim 6 wherein the step of alkylating [Compound 5] comprises reacting [Compound 5] with a 3-(dimethylamino)propyl halogenide.

C. Discussion

(I) Ikemoto Preliminary Motion 2 (Paper 50)

Ikemoto, pursuant to 37 CFR §1.633(g) [now 37 CFR §41.121(a)(1)(ii)], seeks to deny Petersen the benefit of the filing date of Danish Patent Application PA 2000 00296, filed February 24, 2000, for count 1 and Petersen claims 6 and 7 of application 09/794,755.

37 CFR §1.637(g) provides that:

> (g) A preliminary motion to attack benefit under § 1.633(g) shall explain, as to each count, why an opponent should not be accorded the benefit of the filing date of the earlier application.

Ikemoto, as the moving party, bears the burden of proof. 37 CFR §1.637(a).

Ikemoto states that the Petersen Danish patent application does not disclose the subject matter of count 1 or Petersen claims 6 and 7 in accordance with 35 U.S.C. §112, first paragraph. (Paper 50, page 13, first paragraph). More particularly, Ikemoto takes the position that the Petersen Danish patent application does not disclose the last step of the reaction scheme (alkylation to provide Compound 6) (Id., page 14, last 7 lines, and paragraph spanning pages 19-20).

Instead, it is urged, the Petersen Danish application leaves one of ordinary skill in the art with the definitive understanding that the invention of Petersen was a specific reaction scheme of [Compound 5] → [intermediate] → [intermediate] → [Compound 6]

instead of the single alkylation step Compound 5 → Compound 6. (Id., page 20, lines 5-18).

As an initial matter, we note that this motion confuses two separate concepts. Priority benefit in an interference context is different from the applicant's entitlement to a given date for the purpose of determining the patentability of a claim. Priority benefit establishes a date for a party's constructive reduction to practice of the count. See Credle v. Bond, 25 F. 3d 1566, 1673, 30 USPQ2d 1911, 1917 (Fed. Cir. 1994); see also (then effective) rule 37 CFR §1.637(f)(3) (requiring a showing of constructive reduction to practice before awarding benefit of an earlier application).

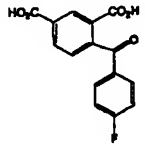
A benefit application need only describe a single enabled embodiment within the scope of the count to constitute a constructive reduction to practice of the invention of the count. Hunt v. Treppschuh, 523 F.2d 1386, 1389, 187 USPQ 426, 429 (CCPA 1975); see also Weil v. Fritz, 572 F.2d 856, 865 n.16, 196 USPQ 600, 608 n.16 (CCPA 1978) As Hunt explains, "the § 112 paragraph, requirements need only be met for an embodiment within the count" where the count is drawn to a genus and the previously-filed application discloses only a species thereof). In establishing benefit for the purpose of priority, it is not necessary to establish that a benefit application complies with the first paragraph of 35 U.S.C. § 112 as to a claim of a party's involved patent or application.

In short, benefit in the sense of 35 U.S.C. §119 or 120 requires an analysis of whether the earlier document complies with 35 U.S.C.§112 to support the claims, while benefit in the interference context (of a motion that another party is not entitled to benefit of priority) requires an analysis of whether the earlier document supports at least an embodiment having the elements of the count.

We observe that there is one count, which recites a method comprising the following steps. That count is reproduced below, and we also note where in the Danish Patent Application support for the step is to be found in bold.

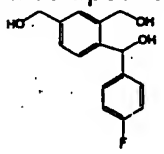
A method for the preparation of citalopram, comprising the steps of:

a) reducing a compound of formula 1



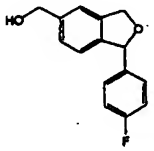
(1) **(Danish Patent Application, page 7 (original page numbers), line 22 et seq.)**

to form a compound of formula 2



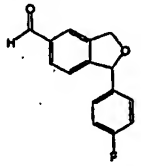
(2) **(Same)**

b) cyclizing or ring closing the compound of formula 2 to form a compound of formula 3



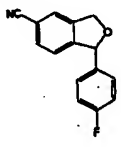
(3) **(Same)**

c) oxidizing the compound of formula 3 to form a compound of formula 4



(4) **(Same)**

d) converting the compound of formula 4 to a compound of formula 5



(5) **(Same)**

and

e) (1) alkylating the compound of formula 5 to form citalopram as an acid or base addition salt thereof, or

e) (2) alkylating the compound of formula 5 to form citalopram; and isolating citalopram in the form of the base or an acid addition salt thereof.[1] **(Page 2, line 11-page 3, line 11).**

Ikemoto's burden, by a preponderance of the evidence, is to establish that Petersen Danish Application does not describe an embodiment within the scope of Count 1. Hunt v. Treppschuh, 523 F.2d 1386, 1389, 187 USPQ 426, 429 (CCPA 1975).

Ikemoto's principal position appears to be that because the Petersen Danish Application discloses extra steps to arrive at the alkylation end result, that it does not disclose the step of alkylating the compound of Count Compound 5 to citalopram.

More specifically, in the nomenclature of Paper 50, "[t]he difference between the reaction scheme recited in Count 1 of the interference and the reaction scheme disclosed in the Petersen Danish application, in terms of the formula numbers recited in Count 1, is '[Compound 5]→ [Compound 6]' (Count 1) versus '[Compound 5] →[Compound 5]+Y → Z →[Compound 6]' (Petersen Danish Application)(Exhibit 1018)" (Paper 50, page 8, lines 4-7). It is evident that the Danish patent application teaches a specific mechanism for alkylation of Compound 5.

This position is not persuasive as regards to the count. Count 1 is written in comprising language, which is fully open to additional steps within the steps. PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). If the count were presumed to be a claim of a patent, the process described in the Danish patent application would infringe that claim. Similarly, if the Danish patent application were prior art to the presumed claim, the claim would be anticipated by the method taught in the Danish patent.

Ikemoto has failed to meet its burden, consequently we shall deny this motion.

[1] In Interference 105,231 reference to the acid addition salts are omitted.

(VIII) Ikemoto Preliminary Motion 3 (Paper 51)

Ikemoto seeks judgment pursuant to 37 CFR §1.633(a) that Claims 6 and 7 of Petersen 09/794,755 are unpatentable under 35 U.S.C. §102(e) as anticipated by Ikemoto Patent 6,433,196. (Paper 51, pages 4-5). More specifically, it is urged that each and every feature of Petersen claims 6 and 7 is disclosed in the prior art Ikemoto '196 patent, rendering these claims unpatentable under 35 U.S.C. §102(e).

We first need to determine if Ikemoto '196 is prior art to Petersen '755. The Petersen '755 application was filed on February 26, 2001. (Paper 51, fact 3; admitted at paper 60, page 3, line 6). The Ikemoto '196 patent issued August 13, 2002 from an application filed September 5, 2000 (Paper 51, fact 4; admitted to this extent in paper 60, page 3, lines 6-8). On its surface, it would appear that Ikemoto '196 is 102(e) art to the Petersen '755 application.

35 U.S.C. §102(e) provides that:

A person shall be entitled to a patent unless-

. . .

(e) the invention was described in ... a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent . . .

Petersen claim 6 recites a method for the production of citalopram, involving the sequence of compounds set out in Finding of Fact 16. Compound 1 is reduced, Compound 2 is ring-closed, Compound 3 is oxidized, Compound 4 is converted, Compound 5 is alkylated, Compound 6 (citalopram) is isolated. (Paper 51, fact 6; admitted at Paper 57, page 3, lines 5-6).

Ikemoto '196 is said to disclose a method of preparing citalopram involving the same compounds, wherein Compound 1 is reduced, Compound 2 is cyclized, Compound

3 is oxidized, Compound 4 is oximated and dehydrated (i.e. converted), and Compound 5 is alkylated. (Paper 51, page 3, fact 7).[2]

Our review of column 2, lines 12-45 reveals that Ikemoto '196 discloses production of the Compound 3 from the Compound 1, but not how this is accomplished. Column 3, lines 19-55 fills in and discloses a reaction of the Compound 1 by reduction and cyclization to yield the Compound 3. Column 9, lines 8-20 reveals that the reduction step from Compound 1 results in the Compound 2. Column 11, line 57 – column 12, line 12 reveals that Compound 3 can be oxidized to Compound 4 with high yield. Column 13, lines 57-column 14, line 30 reveals that Compound 4 may be converted by oximation and dehydration to Compound 5. Finally, column 14, lines 47 et seq. describe the alkylation of Compound 5 to form citalopram, Compound 6.

Accordingly, it appears that the five-step reaction as claimed in Petersen Claim 6 is described by the Ikemoto '196 patent, Petersen's denial of Ikemoto fact 7 notwithstanding.

Petersen Claim 7, alkylating Compound 5 to Compound 6 by reacting the Compound 5 with a 3-(dimethylamino)propyl halogenide is disclosed at column 14, lines 47-51 in the form of the use of 3-(dimethylamino)propyl chloride. Thus, each of the steps is taught to be sequentially desirable and it appears that one of ordinary skill in the art would be taught the specific combinations of Petersen's claims 6 and 7.

To overcome the effect of Ikemoto '196 as 35 U.S.C. §102(e) prior art, Petersen must show a date of invention prior to Ikemoto '196's effective filing date. This can be

[2] Petersen's response to this allegation by Ikemoto is simply "Ikemoto fact 7 is denied" (Paper 57, page 3, line 8). This response does not inform the Board why this fact is denied, leaving us to ferret out why. Ikemoto points to the Ikemoto '196 patent, column 2, lines 12-45, column 3, lines 19-55, and column 9, line 8 through column 16, line 15 in support of Fact 7. This citation is likewise overly general, although less unhelpful.

done by a constructive reduction to practice, e.g. by claiming benefit under §§119 or 120 of an application which describes Petersen's claimed subject matter, or by the filing of a Rule 131 declaration, provided certain procedural threshold issues are met. Petersen has attempted to do both.

(i) Earlier Constructive Reduction to Practice

Whether subject matter claimed in a patent is described in a parent application is a question of fact. In re Alton, 76 F.3d 1168, 1171, 37 USPQ2d 1578, 1580 (Fed. Cir. 1996). Any claims that lack written descriptive support in the original specification of Denmark Application PA 2000-00296 in a manner sufficient to satisfy 35 U.S.C. § 112, paragraph 1 will only be entitled to an effective filing date of February 26, 2001. See 35 U.S.C. § 119 (2002) and Kawai v. Metlesics, 480 F.2d 880, 178 USPQ 158 (CCPA 1973).

Our review of PA 2000-00296 (Exhibits 2008 and 1003) reveals that the 5 step process for going from Compound 1 to Compound 5 is disclosed as another "advantageous method" at page 7, lines 20-40, and from page 2, line 10 – page 3, line 4, the conversion of 5-cyano-1-(4-fluorophenyl)-1,3-dihydrobenzofuran [Compound 5] by alkylation followed by conversion of the alkyl group to a dimethylaminopropyl group to citalopram (Compound 6). Petersen alleges this in Facts 6 -8 of its opposition (Paper 57, pages 4-5, see also Declaration of Jamison, Exhibit 2011).

Ikemoto, on the other hand, urges that Petersen is not entitled to priority because Petersen '755's claims 6 and 7 are a generic multi-step process for preparing Compound 6 (citalopram), while the Petersen Danish application supports only a species of the claimed genus. (Paper 60, page 5, lines 17-20).

Relying on the Federal Circuit's decision in In re Curtis, 354 F.3d 1347, 69 USPQ2d 1274 (Fed. Cir. 2004), Ikemoto states that "an applicant who discloses a species in an earlier application, and then later claims the genus in a subsequently filed patent, is not entitled to priority to the earlier application" (Paper 60, page 5, lines 4-6). We see the Court's opinion in slightly different light, especially in view of Bilstad v. Wakalopulos, recently decided by the Federal Circuit, Docket No. 03-1528, October 7, 2004 (Slip Opinion).

The Federal Circuit's opinion on this point is explained below:

> The question [§112, first paragraph] requires consideration of whether the Bilstad disclosure, as filed, "reasonably conveys to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the earlier filing date." Eiselstein v. Frank, 52 F.3d 1035, 1039 (Fed. Cir. 1995).
>
> With particular relevance to this case, several cases have considered the issue of written description support for an added genus claim when only a species is disclosed. In In re Smythe, our predecessor court said, "We cannot agree with the broad proposition . . . that in every case where the description of the invention in the specification is narrower than that in the claim there has been a failure to fulfill the description requirement in section 112." 480 F.2d 1376, 1382 (CCPA 1973). Smythe involved the question of whether a disclosure of air as a segmentizing medium was sufficient written description to support the broader claim language "inert fluid," though the term "fluid" did not appear in the written description. The court concluded,
>
> > We believe that the use of an inert fluid broadly in this invention would naturally occur to one skilled in the art reading the description of the use of air or other gas as a segmentizing medium to separate the liquid samples. While fluid is a broader term, encompassing liquids, as noted by the solicitor, the specification clearly conveys to one skilled in the art that in this invention the characteristics of a fluid are what make the segmentizing medium work in this invention.
> >
> > This is not a case where there is any unpredictability such that appellants' description of air or other inert gas would not convey to one skilled in the art knowledge that appellants invented an analysis system with a fluid segmentizing medium.

Id. at 1383. Similarly, in In re Rasmussen, 650 F.2d 1212, 1215 (CCPA 1981), our predecessor court considered whether a written description disclosing a single method of applying adhesive supported the amended claim containing the broad language "adheringly applying." The court explained: "[T]hat a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment." Id. The court stated that "one skilled in the art who read Rasmussen's specification would understand that it is unimportant how the layers are adhered, so long as they are adhered." Id. Thus, our predecessor court recognized that disclosure of a single species within a genus may be enough support for a claim directed to the genus.

In Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575-77 (Fed. Cir. 1985), this court affirmed a trial court's finding that several open-ended ranges were supported by a parent written description. In particular, this court affirmed the trial court's conclusion that the limitation "protein content of at least about that of solvent extracted soybean meal" was supported by the written description disclosing solvent extracted soybean meal with a protein content of about 50%. Id. at 1575-76. Although open-ended and although the parent disclosure did not teach materials having greater than 50% protein content, this court said, "The trial court found that the parent disclosure does support the claim language, based on the 1964 disclosure and on consideration of the knowledge possessed by those skilled in the art of extrusion of both farinaceous and proteinaceous vegetable materials in 1964." Id. at 1576. We then noted that soybean meals with protein contents above 50% were readily available commodities in 1964. We concluded that "the court did not clearly err in determining that the parent's disclosure adequately supports the protein content of the claims in issue." Id. at 1576.

Thus, this court has continued to apply the rule that disclosure of a species may be sufficient written description support for a later claimed genus including that species. As we explained in Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.:

> Claim 1 was properly rejected because it recited an element not supported by Fox's disclosure, i.e., a lockout "on the stapler." It does not follow, however, that Fox's disclosure could not support claims sufficiently broad to read on a lockout off of the cartridge. If Fox did not consider the precise location of the lockout to be an element of his invention, he was free to draft claim 24 broadly (within the limits imposed by the prior art) to exclude the lockout's exact location as a limitation of the claimed invention. Such a claim would not be unsupported by the specification even though it would be literally infringed by undisclosed embodiments.

93 F.3d 1572, 1582 n.7 (Fed. Cir. 1996) (citations omitted); see also Lampi Corp. v. Am. Power Prods., Inc., 228 F.3d 1365, 1377-78 (Fed. Cir. 2000) (affirming the district court's finding that disclosure of only identical half-shells was

> sufficient written description support for a claim encompassing both identical and non-identical half-shells).
>
> There are, however, exceptions to the general rule that disclosure of a species provides sufficient written description support for a later filed claim directed to the genus. For example, in the recent case of In re Curtis, 354 F.3d 1347 (Fed. Cir. 2004), this court affirmed the Board's rejection of claims directed to dental floss for failure to satisfy the written description requirement. The relevant parent application only disclosed the use of microcrystalline wax as adhered to polytetrafluoroethylene floss. However, the claims in the continuation-in-part application were more broadly drawn to the genus of friction enhancing coatings applied to polytetrafluoroethylene floss. This court explained that the evidence relied on by the Board in determining that the later claims were not entitled to priority to the parent application indicated that at the time the parent application was filed no one knew of any material other than microcrystalline wax that would adhere to the polytetrafluoroethylene floss. Id. at 1352-53. This court then distinguished In re Smythe by explaining that the Board properly found that this particular field was unpredictable. "Unlike the circumstances In re Smythe presented, the instant facts present a case in which there is 'unpredictability in performance of certain species or subcombinations other than those specifically enumerated.'" Id. at 1355 (quoting In re Smythe, 480 F.2d at 1383). Thus, unpredictability in the particular field may warrant closer scrutiny of whether disclosure of a species is sufficient to describe a genus.
>
> The distinction in these cases is based upon what would be reasonably conveyed to a person skilled in the art at the time of the original disclosure. If the difference between members of the group is such that the person skilled in the art would not readily discern that other members of the genus would perform similarly to the disclosed members, i.e., if the art is unpredictable, then disclosure of more species is necessary to adequately show possession of the entire genus.
>
> Another exception is presented in Tronzo v. Biomet, Inc., 156 F.3d 1154 (Fed. Cir. 1998). In Tronzo, this court held that substantial evidence did not support the jury's verdict that claims to a hip prosthesis of generic shape were supported by a parent disclosing only a trapezoidal shape. We said, "Instead of suggesting that the '589 patent [the parent] encompasses additional shapes, the specification specifically distinguishes the prior art as inferior and touts the advantages of the conical shape of the '589 cup. Such statements make clear that the '589 patent discloses only conical shaped cups and nothing broader." Id. at 1159 (citation omitted).

(Slip Opinion at pages 12-16).

In order to prove its entitlement to priority, Petersen must show us that one skilled in the art, reading the original disclosure, must reasonably discern the limitation at issue

in the later claims. Waldemar Link GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558, 31 USPQ2d 1855, 1857(Fed. Cir. 1994). A disclosure that merely renders the later-claimed subject matter obvious to one of ordinary skill in the art at the time of the invention is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations. Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158, 47 USPQ2d 1829, 1832 (Fed. Cir. 1998); Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). "That a person skilled in the art might realize from reading the disclosure that such a step is possible is not a sufficient indication to that person that that step is part of appellants' invention." In re Barker, 559 F.2d 588, 593, 194 USPQ 470, 474 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978)(quoting In re Winkhaus, 527 F.2d 637, 640, 188 USPQ 129, 131 (CCPA 1975)).

We need to discuss several things in rendering our decision. First, we need to establish the level of ordinary skill in the art. Second, we need discuss the predictability of the art and its impact on one of ordinary skill in the art. Third, we need to address whether the Danish application disclaimed any of the species which are now claimed.

Petersen and Ikemoto assert that one of ordinary skill in the art as of February 24, 2000 would have been either (I) a person with at least a bachelor's degree in chemistry with specialty in organic synthesis; and 1-2 years of experience in organic synthesis if not that specialty (Exhibit 2011, paragraph 4) or (II) a person with a BS degree in chemistry (Exhibit 1019, paragraph 3). The two are rough equivalents. This person would have a working knowledge of synthesis reactions and mechanisms involved in complex organic synthesis schemes.

Second, we examine the predictability of the art. Petersen's expert, Dr. Timothy Jamison, has testified to this. He states ". . . (iii) alkylations of organic compounds such as [Compound 5] are relatively predictable and easy to accomplish" (Exhibit 2011, paragraph 42, last two lines). Dr. Jamison had earlier in his declaration pointed to a general alkylation of diphenylmethane as similar to alkylation of Compound 5, citing the Streitweiser text (Exhibit 2011, paragraphs 13 and 14).

We also turn to the application itself. The Danish parent application (Exhibit 2008) states, at page 2, lines 1-3, that:

> It has now, **surprisingly**, been found that citalopram may be manufactured by a novel favourable process where 5-cyano-1-(4-fluorophenyl)-1,3-dihydrobenzofuran [Compound 5] is alkylated with a compound which may be converted to a dimethylaminopropyl group. (emphasis added)

The Petersen US Application (Exhibit 1002), as filed, altered from that original statement in the Danish parent application, at page 2, lines 4-7, states that:

> It has now, **surprisingly,** been found that citalopram may be manufactured by a novel favourable process via 1-(4-fluorophenyl)-1,3-dihydrobenzofurane-5-formaldehyde prepared by ring closure of 2,4-dihydroxymethyl-1-[1-(4-fluorophenyl)-1-hydroxy-1-methyl]benzene and oxidation of the resulting 5-hydroxymethyl – 1(4-fluorophenyl)-1,3-duhydroisobenzofuran [sic]. (emphasis added)

These paragraphs occur at the end of the section entitled "Background of the invention" which describes certain prior art and known methods for manufacturing citalopram. In the Danish parent application, the evidence shows that the prior art methods of DE 2,657,271; US 4,136,193; and WO 98/019511 are "surprisingly" different from the alkylation and conversion step of PA 2000 00296. Accordingly, on balance we conclude that this "surprisingly" discovered process militates against the promise of predictability urged by Dr. Jamison. In this regard, we credit the statements in the Danish

and present application over those of Dr. Jamison. The art is, on this record, apparently unpredictable as regards alkylation.

We also observe that Exhibit 2008, the parent, is written much more narrowly in describing the invention. It discusses such things as being particularly advantageous in giving high yields, and polymerization of the alkylating agent is avoided causing a reduction in the amount of alkylating agent. (Page 5, lines 5-8).

We find that this language contained in the parent disfavors admitted prior art alkylation methods which are not manufactured by the "favourable" two-step method of alkylating and then converting the alkylated compound. Consequently, we ascribe some intent to distance those methods from this disclosure. While the Petersen Danish application can be said to "disclose" these prior art methods, including alkylating the 5-cyano derivative (Compound 5) with 3-dimethylamino propylhalogenide in order to obtain citalopram, one of ordinary skill in the art, reading this "disclosure," would not discern the generic alkylation as a claim limitation or as part of the Danish application's invention.

Dr. Silverman's Declaration (Exhibit 1019) concludes that the Petersen Danish application does not describe the general alkylation step recited in Petersen claim 6 nor the specific alkylation step recited in Petersen claim 7. (Exhibit 1019, Paragraph 15). This is based upon the "favourable" alkylation process of alkylation then conversion (Exhibit 1019, Paragraph 8) and the disclosure that the preparation of Compound 5 from Compound 1 is not presented as a route to prepare citalopram, but rather as a route to prepare Compound 5 (Exhibit 1019, Paragraph 12).

We credit most of Dr. Silverman's Declaration. The invention as claimed in the Petersen Danish application discloses the reaction scheme from Compound 1 to Compound 5 as a method of arriving at compound 5. (Exhibit 1019, paragraph 12). There is no doubt that the 5 step process is disclosed at page 7, lines 20-40 of Exhibit 2008. We disagree with Dr. Silverman's conclusion that this "reaction scheme is *not* presented as a route to prepare [Compound 6] but rather as a route to prepare [Compound 5]." (Id., last 2 lines, emphasis in original). As the entire Danish patent application disclosure is directed to the preparation of Compound 6 - citalopram (see, e.g. the title and page 1, first 10 lines), we find that one of ordinary skill in the art would discern that the 5 step reaction scheme is only part of the reaction scheme to acquire Compound 6. It is in combination with the sixth step that the invention resides, and the Petersen Danish application describes 5 + 1 steps.

Petersen urges that the Petersen Danish application discloses at least three different alkylation methods (Paper 57, Fact 9) which would be this sixth step and as a consequence a generic step is described. These include: (i) alkylation by reacting Compound 5 with 3-(dimethylaminopropyl) halogenide in the presence of a condensing agent, such as alkali amide or methylsulfinylmethide, to form citalopram, (ii) alkylation with 3-(dimethylaminopropyl) halogenide in basic conditions using lithiumdiisopropylamide (LDA) to form citalopram, and (iii) alkylation by reacting Compound 5 with another compound to form an intermediate compound which is then converted to Compound 6 - citalopram.

Ikemoto asserts that ". . . the disclosure of the specific two-step alkylation process in the Petersen Danish application cannot be treated as a disclosure of a genus of

alkylation processes that include prior art alkylation processes that are allegedly less favorable and not so advantageous. . . " (Paper 60, page 6, last 4 lines). In support of this Ikemoto relies on Exhibit 1019, the declaration of Dr. Silverman, which points out that the Danish application is specific in stating the invention has advantages in that the polymerization of the alkylation agent is avoided, which is better than the prior art single step process. (Exhibit 1019, Paragraph 8).

The crucial question is whether the various alkylation steps which are disclosed in the Danish application to go from compound 5 to compound 6 are sufficient to support a claimed genus encompassing all alkylation steps for going from compound 5 to compound 6.

Dr. Silverman states that the Petersen Danish application " . . . describes the invention as the conversion of [Compound 5] to citalopram by way of reacting [Compound 5] with [an alkyl chain] to form [a precursor to citalopram], which is then converted to [Compound 6]. . . " (Exhibit 1019, paragraph 14). Dr. Silverman concludes : " . . . the Petersen Danish application does not describe the general alkylation step recited in Petersen claim 6 (" [Compound 5] -> [Compound 6]"), nor does it describe the specific alkylation step recited in Petersen claim 7 ("[Compound 5] + 3-(dimethylamino)propyl halogenide -> [Compound 6]").

On Petersen's side, we find Dr. Jamison's declaration (Exhibit 2011) to be informative on the issue as to whether a person of ordinary skill in the art would find the Danish application description sufficient. Paragraphs 15 and 16 explain that the Petersen Danish application describes (expressly or by reference to other publications) three different methods of alkylation, and that one of ordinary skill in the art at the time the

Danish application was filed "could have used these, or any other, alkylation methods to convert Compound I into citalopram." (Exhibit 2011, paragraph 16, lines 2-3).

The problem with this statement is that if we assume that the use of these methods may have been obvious to one of ordinary skill in the art at the time the invention was made, this statement does not support the conclusion reached in paragraph 34, that the description of the Petersen Danish patent application adequately shows that the inventors had invented the process for preparing citalopram called for in pending claim 6.

The declaration of Jamison (Exhibit 2001) stitches together portions of the description of the Petersen Danish parent application, but the pattern is different from that created by the original weaver. The disclosure of step 6 is limited to the "novel favourable" step 6 – the alkylation and conversion with concomitant benefits. Petersen now seeks to capture the generic alkylation, which, according to the Danish application, is less favorable than the two-step process of high yield and less waste due to polymerization.

We decline to credit, and expressly reject, Dr. Jamison's conclusions of paragraph 10 – that the method of pending claims 6 and 7 is described to one of ordinary skill in the art. To the extent that this conclusion is based on the penultimate line of that paragraph, that a person of ordinary skill in the art could have "successfully performed the steps of the disclosed method without undue experimentation and with a reasonable expectation of success" we observe that this seems to be implying that an obviousness-type standard be used. Such a standard is inappropriate in light of the guidance of the Federal Circuit on this issue in Tronzo and Lockwood.

For example, the statements of paragraph 12, 13, 14, 16, 23, 27, 30, and 31 which are phrased in terms of a "reasonable expectation of success" or "without undue experimentation" are unpersuasive because they do not establish that one of ordinary skill in the art would have recognized that the inventors actually invented that which is claimed.

The multiple methods of alkylation, which Petersen assert support the generic claim, are differentiated in the Danish parent application as somewhat less than favorable. Thus, relying on the disclosures of DE 2,657,271; US 4,136,193, or WO/98/019511 (as is done in paragraphs 15, 17, 18, 19, 20, 21, 22, 23) is inappropriate for determining whether the description supports a generic alkylation step. The Petersen Danish application discusses those prior art methods and then favorably compares the invention of the two-step alkylation against them. This is a "disclaimer" of the prior art methods of alkylating which were not considered by the inventor to be part of the described invention.

Certainly, the disclosure of the Petersen Danish application may render the claimed subject matter obvious to the skilled artisan. But one of ordinary skill in the art at the time of the original disclosure would have understood that the two-step process is different from the other now claimed genus members. As a consequence, the person skilled in the art would not readily discern that other members of the genus would perform similarly to the disclosed members.

In sum, we observe that Petersen has not established that the Danish patent application sufficiently describes the invention of either claim 6 or 7 for at least the reasons that:

(1) the field of alkylation of Compound 5 is not predictable. Petersen has twice stated in applications that surprising results were obtained by a particular mechanism. The now asserted position that these mechanisms are "relatively predictable" (Exhibit 2011, paragraph 42) is insufficient to establish predictability such that one species of the claimed genus gives possession of the entire genus.

(2) Petersen has "disclaimed" the prior art alkylation as not being as favorable as the two-step process outlined in the Danish patent application. One of ordinary skill in the art would recognize that the less favorable prior art alkylation was not part of the invention.

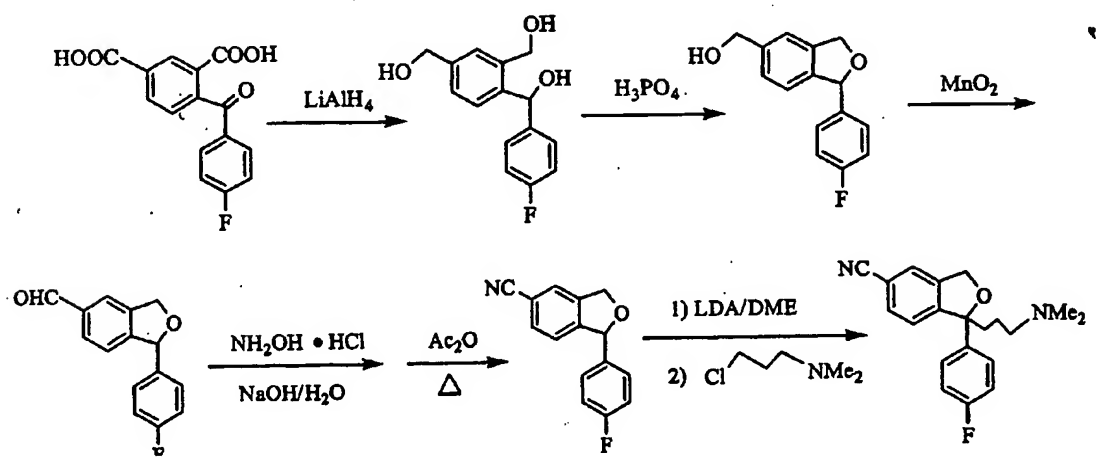
We find under the facts of this interference, that disclosure of more species, beyond the two-step alkylation processes described in the Danish Patent application as part of the invention, is necessary to adequately show possession of the entire genus. The Danish patent application fails to do this and as a consequence does not antedate the Ikemoto '196 patent.

(ii) Petersen's Declaration Under 37 CFR §1.131

We now turn to Petersen's contention that the inventors had invented the claimed subject matter prior to the filing date of the Ikemoto Patent by virtue of the 5 laboratory notebook pages, signed and dated by Petersen, in Denmark. We observe that the Rule 131 Declaration (Exhibit 2016) establishes very little. Of the 6 paragraphs, paragraph 1 establishes inventor Petersen's identity, and paragraph 6 establishes his awareness of the penalties for perjury. Paragraphs 2 and 3 recite the limitations of Petersen claims 6 and 7. Paragraph 4 is conclusory – "I had possession of these methods of making citalopram, as recited in claims 6 and 7 of the Petersen '755 application, prior to September 5, 2000."

Paragraph 5 identifies Attachment A – 5 laboratory notebook pages in Danish. It does not state who conducted the experiments or provide any background information on the documents. We simply are informed that there are 5 pages in Danish, signed and dated by inventor Petersen, along with a translation, which "show[] my possession of the methods recited in claims 6 and 7 of the Petersen '755 application. . . prior to September 5, 2000".

Petersen's Opposition (Paper 51, page 7, paragraph 15) urges (in much greater detail than the Rule 131 declaration) that Petersen signed and dated five laboratory notebook pages that illustrate the methods of preparing citalopram called for in claims 6 and 7, including the following reaction scheme:



Petersen does not point us to anything other than Declaration Exhibit A in its entirety in support of this reaction scheme.

Initially, we observe that nowhere in this exhibit does the reaction scheme as outlined in paper 51, fact 15 appear. It seems that Petersen desires us to knit the story together on our own. We attempt to do so below.

We turn to the original pages to glean what information we can. We see what appear[3] to be pages of laboratory notebook number 223. The pages in particular appear to be 192, 193, 195, 196, and 183. The respective dates appear to be September 22, 1997, September 23, 1997, September 25, 1997, September 26, 1997, and September 1, 1997. The pages appear to be signed and witnessed on either October 10, 1997 and October 14, 1997.

We next turn to the translated pages. Page 192 appears to disclose forming Compound 2 from Compound 1. Page 193 appears to show the formation of Compound 3 from Compound 2. Page 195 appears to show formation of Compound 4 from Compound 3. Page 196 appears to show formation of a final yield of two grams of Compound 5 from Compound 4. It is reasonable to assume that these occurred sequentially in their order as written.

However, page 183 is apparently relied upon to show the alkylation of Compound 5 to form Compound 6. The notebook shows, if the pagination is to be believed, that the final step appears to have occurred prior to the other 5 steps. We are also not informed as to what the missing pages include. Could they show other alkylations?

Furthermore, the final alkylation was conducted with what appears to be 62 grams of Compound 5. This amount of Compound 5 could not have come from the reaction of Page 196, which apparently yielded only 2 grams of Compound 5. These discrepancies

[3] By use of the word "appear" we indicate an assumption on our part, as Petersen has not pointed to evidence supporting these conclusions. We make these assumptions, not findings of fact, in an effort to see if Petersen under the best of circumstances could have antedated the Ikemoto '196 patent disclosure by reference to these notebook pages in his declaration.

are not addressed at all, and we are simply urged to conclude that the 6 steps disclosed in the notebook are the 6 claimed steps in the claimed order.

Rule 131 (b) provides that for Rule 131 affidavits, that:

> The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained.

We conclude that the evidence of the Petersen Declaration is insufficient in character and weight to establish that the subject matter of claims 6 and 7 had been reduced to practice prior to the effective date of Ikemoto '196. It does not establish the steps of the six step method were conducted in the order claimed.

Furthermore, even were we to assume the connections that Petersen urges us to make, the evidence in its best possible light only shows the following:

forming compound 2 from compound 1 using $LiAlH_4$ for reduction,

forming compound 3 from compound 2 using H_3PO_4 for ring closure,

forming compound 4 from compound 3 using MnO_2 for oxidation,

forming compound 5 from compound 4 using NH_2OH*HCl and $NaOH/H_2O$ with heat in the presence of Ac_2O, and

forming compound 6 from compound 5 using LDA/DME to alkylate with 3-(dimethylamino) propyl chloride.

These are five very specific steps when compared to Claims 6 and 7, which are generic in each step. A rule 131 affidavit needs to show as at least as much of the claimed invention as the intervening reference discloses. See, e.g. In re Stempel, 241

F.2d 755, 760, 113 USPQ 77, 81 (CCPA 1957). The Ikemoto '196 patent discloses a multitude of reagents to accomplish the claimed generic steps. The scant evidence proffered by Petersen, to the extent any weight can be given it, illustrates a single species of generic claim 6, which is more than blanketed by the overarching disclosure of the Ikemoto reagents.

Furthermore, Petersen has on two separate instances urged that different species of the genus result in surprising results. Put simply: we find that the narrow species, on the facts before us, is not commensurate with the all-inclusive alkylation genus of Claim 6. The question of commensurateness is a closer question as regards claim 7. However, on balance, based upon the facts of this interference, we conclude that Ikemoto's disclosure of multiple reagents for the first four steps of the process requires more than a single narrow species from Petersen to establish possession of the otherwise generically claimed subject matter of claim 7 as well.

Accordingly, as Petersen has not effectively antedated the filing date of US Patent 6,433,196, and the '196 patent is prior art under 35 U.S.C. §102(e) disclosing the claimed subject matter, we determine that Ikemoto has met the burden of establishing that claims 6 and 7 of Petersen 09/794,755 are unpatentable under 35 U.S.C. §102(e) as anticipated by US Patent 6,433,196. The burden then shifted to Petersen to antedate the filing date of the '196 patent. Petersen has failed to carry its burden. Therefore, Ikemoto Preliminary Motion 3 is **GRANTED**.

It is hereby **ORDERED** that:

Ikemoto Preliminary Motion 2 is DENIED.

Ikemoto Preliminary Motion 3 is GRANTED.

mck

FRED E. McKELVEY
Senior Administrative Patent Judge

RICHARD E. SCHAFER
Administrative Patent Judge

JAMES T. MOORE
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS
) AND
) INTERFERENCES

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